

**IN UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

NIGEN BIOTECH, LLC, a Nevada limited  
liability company

Plaintiff,

VS.

GREGG ABBOTT, as the ATTORNEY  
GENERAL OF THE STATE OF TEXAS

Defendant.

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CIVIL ACTION NO. 3:11-cv-03341-G

**PLAINTIFF'S FIRST AMENDED COMPLAINT**

**INTRODUCTION**

This case is about the use of the letters “HCG” on the packaging and labeling of two dietary supplement weight control products, Isodrene Weight Loss Solution with HCG Isolates (“Isodrene”) and The HCG Solution (“The HCG Solution”) (together the “Products”). It is undisputed that 1) the Products are effective for weight control, 2) the Products properly are labeled as dietary supplements, 3) that the ingredients in the Product are legal for sale, and 4) all statements on the Product box and label are true. Nevertheless, Defendant has, in violation of Plaintiff’s constitutional rights, effectively stopped the sale of the Products in Texas by threats and intimidation of Plaintiff’s customers, including WalMart, Walgreens, and CVS.

In a letter dated October 26, 2011, Defendant made two unsupported arguments that it claims justify its illegal actions. First it says it is “false, misleading, or deceptive to advertise and sell a dietary supplement whose name includes that of a prescription drug”.

Defendant's first argument fails for at least two reasons. A) If it is the position of the State of Texas that the names of prescription drugs cannot be included on the label or in

advertising for anything but prescription drugs, thousands of foods, vitamins, and other products would require immediate recall because there are a vast number of “prescription drugs” that also are dietary supplement ingredients. Examples include all of the essential nutrients, such as iron, potassium, calcium, and even something as common as sodium chloride (salt).

B) The notion that a purchaser could be misled to believe that either Isodrene or The HCG Solution contain a prescription drug is absurd. Both Products are clearly marked as “Dietary Supplements.” And both Products can be purchased by any consumer in a local WalMart, grocery store, or other retailer off the shelf *without* a prescription. Therefore, no one could believe the Products were or are prescription drugs.

Defendant's second assertion in its letter that “using the term hCG on a weight loss product, even with a disclaimer that hCG is not really in the product is false, misleading, or deceptive since this claim is trying to mimic claims that FDA considers off-label for the prescription drug” is baseless.

Defendant's second argument fails because the packaging for both Isodrene and The HCG Solution contain statements *supporting* the FDA’s position that there is no proven weight loss benefit to hCG. For example Isodrene’s label clearly states “HCG has no proven weight loss benefit.”

Instead of relying on hCG for their weight loss claims, the Products contain active weight loss ingredients that have been clinically validated in double blind placebo controlled published trials and have been reviewed by some of the world’s leading experts in the obesity and weight loss field. In fact, it is uncontested by Defendant that consumers of the Products are using validated weight loss formulas.

Defendant has no basis to prevent the sale of the Products in the State of Texas. Nevertheless, Defendants has threatened Plaintiff and its customers with millions of dollars in fines. As a result of the Defendant's threats, WalMart removed The HCG Solution from its stores in Texas, and Walgreens removed Isodrene from its stores nationwide. Defendant's actions violated the Plaintiff's constitutional rights and have caused significant damage to the Plaintiff.

**PARTIES, JURISDICTION, AND VENUE**

1. Plaintiff is a Nevada limited liability company.
2. Gregg Abbott is the Attorney General of the State of Texas. He may be served with process at 300 West 15th Street, 9th Floor, Austin, Texas.
3. This action is brought pursuant to the Interstate Commerce Clause of the United States Constitution (Article 1 § 8), the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, the Due Process Clause of the Fourteenth Amendment to the United States Constitution, and the Free Speech Clause of the First Amendment to the United States Constitution.
4. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1343, 1367, and 2201.
5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events or omission giving rise to the claim in this complaint occurred in the Northern District of Texas.

## **GENERAL ALLEGATIONS**

### **ISODRENE AND THE HCG SOLUTION**

6. Plaintiff manufactures, distributes, and sells Isodrene and The HCG Solution throughout the United States. The Plaintiff sells both products in liquid and pill form.

7. Both products contain ingredients that have been demonstrated in double blind placebo controlled studies to cause weight loss.

8. The HCG Solution contains ingredients that have been proven in double blind placebo controlled studies to cause weight loss. These ingredients are cissus quadrangularis, caffeine, and green tea extract.

9. Isodrene contains ingredients that have been proven in double blind placebo controlled studies to cause weight loss. These ingredients are ilex paraguariensis, paulinia cupana, and turnera diffusa.

10. The Products' labels clearly state, as required by Federal law, that they each are a "Dietary Supplement".

11. The labels for each Product contain only true claims.

### **HUMAN CHORIONIC GONADOTROPIN**

12. Human chorionic gonadotropin hormone ("hCG") is a naturally occurring hormone found in the bodies of most pregnant women and is an ingredient in prescription drugs sold under the brand names Noverel, Ovidrel and Pregnyl.

13. Isodrene and The HCG Solution contain the individual amino acid building blocks of hCG, but neither contains the human chorionic gonadatropin hormone, as they are labeled "100% Hormone Free", and may therefore be sold without a prescription.

### **“HCG” DIET PLANS**

14. In 1954, British endocrinologist Dr. A.T.W. Simeons published an article entitled “Pounds and Inches: A New Approach to Obesity.” In that article, Dr. Simeons advocated the use of the hCG hormone combined with a special reduced calorie diet to induce significant weight loss in obese individuals.

15. Popularity of the “HCG” diet spread and in the 1970’s and 1980’s in the United States, numerous “HCG” products and “HCG Diet Plans” became popular. Today there are countless “HCG” products and “HCG Diet Plans” available on the market.

16. HCG diet plans, which include very low calorie diets have been shown to be effective in assisting people lose weight. However, there is no evidence that the combination of hCG and very low calorie diets show any greater weight loss than very low calorie diets alone.

17. Today, the letters “HCG” and the phrase “HCG diet plans” are associated with effective weight loss.

### **Formulation of Isodrene and The HCG Solution**

18. Plaintiff developed Isodrene and The HCG Solution to be sold as dietary supplements.

19. Plaintiff formulated Isodrene and The HCG Solution to contain the full spectrum of hCG amino acid isolates found in the hormone. Both Isodrene and The HCG Solution contain, in their pure form, all of the amino acids in the same proportions as the human chorionic gonadatropin hormone, but remain completely hormone free.

20. The amino acid sequence of the alpha and beta subunits of the HCG variants was determined in the 1970s. The alpha subunit contains 92 amino acids and the beta subunit contains 145 amino acids as follows:

Alpha-subunit:

ala-pro-asp-val-gln-asp-cys-pro-glu-cys-thr-leu-gln-glu-asp-pro-phe-phe-ser-gln-pro-gly-ala-pro-ile-leu-gln-cys-met-gly-cys-cys-phe-ser-arg-ala-tyr-pro-thr-pro-leu-arg-ser-lys-lys-thr-met-leu-val-gln-lys-asn-val-thr-ser-glu-ser-thr-cys-cys-val-ala-lys-ser-tyr-asn-arg-val-thr-val-met-gly-gly-phe-lys-val-glu-asn-his-thr-ala-cys-his-cys-ser-thr-cys-tyr-tyr-his-lys-ser

Beta-subunit:

ser-lys-glu-pro-leu-arg-pro-arg-cys-arg-pro-ile-asn-ala-thr-leu-ala-val-glu-lys-glu-gly-cys-pro-val-cys-ile-thr-val-asn-thr-thr-ile-cys-ala-gly-tyr-cys-pro-thr-met-thr-arg-val-leu-gln-gly-val-leu-pro-ala-leu-pro-gln-val-val-cys-asn-tyr-arg-asp-val-arg-phe-glu-ser-ile-arg-leu-pro-gly-cys-pro-arg-gly-val-asn-pro-val-val-ser-tyr-ala-val-ala-leu-ser-cys-gln-cys-ala-leu-cys-arg-arg-ser-thr-thr-asp-cys-gly-gly-pro-lys-asp-his-pro-leu-thr-cys-asp-asp-pro-arg-phe-gln-asp-ser-ser-ser-ser-lys-ala-pro-pro-pro-ser-leu-pro-ser-pro-ser-arg-leu-pro-gly-pro-ser-asp-thr-pro-ile-leu-pro-gln.

KEY: ala=Alanine

arg=Arginine

asn=Asparagine

asp=Aspartic acid

cys=Cystenine

glu=Glutamic Acid

gln=Glutamine

his=Histidine

hyp=Hydroxyproline

ile=Isoleucine

leu=Luecine

lys=Lysine

met=Methionine

phe=Phenylalanine

pro=Proline

ser=Serine

thr=Threonine

tyr=Tyrosine

val=Valine

21. The Products are formulated with the full spectrum of hCG amino acid isolates.

When a protein is ingested, a hormone called pepsin, contained in the stomach, begins to fragment the protein into peptides. Enzymes in the pancreatic juice continue the peptide digestion, and finally the peptidases split the peptides into their amino acid isolates that can be absorbed. Since this is the process by which the hCG hormone would be digested, the Products were formulated as a safe and bio-available means to obtain the same amino acid isolates.

22. Because the amino acids in Isodrene and The HCG Solution are in their pure form in the same proportions as found in the hCG hormone, relative to their isolated amino acids, both Isodrene and The HCG Solution are at least the functional equivalent of human chorionic gonadatropin hormone when ingested orally.

23. In addition, the amino acids in Isodrene and The HCG Solution are in a form that should be as, or more, bioavailable than that found in human chorionic gonadatropin hormone ingested orally.

24. Isodrene and The HCG Solution products do not claim to contain the chorionic gonadatropin hormone found in the prescription drugs Noverel, Ovidrel and Pregnyl. Nor do the Products claim to be equivalents to the prescription drugs Noverel, Ovidrel and Pregnyl. Indeed,

both Isodrene and The HCG Solution contain the prominently displayed disclaimer “100% Hormone-Free.”

## ISODRENE AND THE HCG SOLUTION PACKAGING

25. The Isodrene packaging is as follows:



26. The only weight loss claim made regarding Isodrene Weight Loss Formula is that “the active Isodrene weight loss compound is a combination of *Ilex paraguariensis*, *paullinia coupuna*, and *turnera diffusa*.” This is a true statement.



30. Although no express weight loss claim is made regarding The HCG Solution, there is an implied weight loss claim as the letters “HCG” are associated with weight loss products, and the product is sold in the weight loss section of retailers. To support the implied weight loss claims, The HCG Solution contains ingredients that have been shown in clinical published double blind placebo controlled studies to show significant weight loss.

31. The HCG Solution packaging states that it is “%100 Hormone Free” and therefore does not contain human chorionic gonadatropin hormone; however, it does contain the full spectrum of human chorionic gonadatropin amino acid isolates. That is a true statement.

32. The HCG Solution packaging states: “NiGen Biotech guarantees that its branded ‘HCG Solution’ contains the full spectrum of human chorionic gonadatropin amino acid isolates derived certified grade raw materials (the very purest materials available) which are then processed according to GMP (Good Manufacturing Practices), is made in the U.S.A. and is hormone free.” That is a true statement.

33. The HCG Solution Packaging also makes clear that there is a great deal of controversy regarding the efficacy of “HCG diet plans”:

But do any of them really work? To tell you the truth, almost every expert will say either “absolutely not”, “the reduced calorie diet plan caused the weight loss” or “the weight loss was the result of the placebo effect.”

34. The HCG Solution contains a very low calorie diet plan and directs them to additional HCG diet plan information on a website to assist consumers with their weight loss efforts.

#### **Accusations Regarding DTPA Violations**

35. On October 26, 2011, the Office of the Attorney General of Texas sent Plaintiff a letter (the “Letter”).

36. The Letter alleges that Plaintiff's marketing of Isodrene and The HCG Solution violates provisions of the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. and Com. Code § 17.41 et seq. (the "DTPA").

37. The Letter alleges that: "It is the State's opinion that it is false, misleading, or deceptive to advertise and sell a dietary supplement whose name includes that of a prescription drug."

38. If it is the position of the State of Texas that the names of prescription drugs cannot be included on the label or in advertising for anything but prescription drugs, thousands of foods, vitamins, and other products would require immediate recall because there are a vast number of "prescription drugs" that also are dietary supplement ingredients. Examples include all of the essential nutrients, such as iron, potassium, calcium, and even something as common as sodium chloride (salt).

39. Furthermore, no purchaser would ever believe that the Products contain prescription drugs when they can walk into a local WalMart, grocery store, or other retailers and purchase the product off the shelf without a prescription. The Products are clearly marked "Dietary Supplement"; thus, consumers know without a doubt that the Products do not contain prescription drugs.

40. The Letter further alleges that "using the term hCG on a weight loss product, even with a disclaimer that hCG is not really in the product, is false, misleading, or deceptive since this claim is trying to mimic claims that FDA considers off-label for the prescription drug."

41. In fact the products advance the FDA's position with the following statement on the advertising, box, and label:

"HCG has no proven weight loss benefit."

and

There are literally thousands of brands and hundreds of combinations of orally administered so-called HCG products to be had. But do any of really work? To tell you the truth, almost every expert will say either “absolutely not”, “the reduced calorie diet plan caused the weight loss” or “the weight loss was the result of the placebo effect.”

42. In any event, both Isodrene and The HCG Solution contain active weight loss ingredients that have been clinically validated in double blind placebo controlled published trials, and have been reviewed by some of the world’s leading experts in the obesity and weight loss field. Thus, consumers are purchasing validated weight loss formulas.

43. The Letter indicates that Plaintiff’s actions, “at a minimum,” violate Sections 17.46(b)(2), (5), (7), and (24) of the DTPA.

44. The Letter also indicates that: “It is also the State’s position that each sale of NiGen’s hCG-labeled products as dietary supplements or over-the-counter drugs into Texas is a separate violation of the DTPA.”

45. The Letter warns that the State may seek damages, including millions of dollars of civil penalties and restitution of all money paid by purchasers of Isodrene and The HCG Solution, an injunction, and attorney’s fees, investigative fees, and costs.

46. Finally, the Letter states that “it is the State’s position that NiGen cannot legally advertise or sell its hCG-labeled products in Texas and that NiGen must stop advertising and selling these products in Texas.”

47. Contrary to the Defendant's position, Plaintiff does not sell HCG labeled products. Instead, the Products are labeled as dietary supplements and truthfully state they contain the full compliment of amino acids that make up human chorionic gonadotropin.

48. Based upon its claim that Isodrene and The HCG Solution product packaging violates federal law, the Defendant intends to immediately remove Isodrene and The HCG Solution from retailers' shelves across Texas and to stop the Plaintiff from selling the products directly to Texas residents.

49. Plaintiff's product packaging does not violate Federal or Texas law. Accordingly, the Defendant does not have any legal basis to seek removal of the products from Texas.

50. The Defendant contacted the Plaintiff's customers, including WalMart, CVS, and Walgreens and threatened them with ruinous fines if they continued to sell the Plaintiff's products.

51. As a direct result of the Defendant's threats, WalMart removed the HCG Solution from shelves in Texas, and Walgreens removed Isodrene Weight Loss Formula with HCG Isolates from its stores nationwide.

### **FIRST CLAIM FOR RELIEF**

#### **(Declaratory Judgment)**

52. Plaintiff incorporates the above paragraphs herein.

53. There is a justiciable controversy based upon an accrued set of facts because the Defendant has alleged that Plaintiff has violated Federal law, which alleged violation the Defendant claims gives rise to a violation of the DTPA.

54. There is an actual conflict because Plaintiff disputes, among other claims, Defendant's claims that Plaintiff has violated Federal law or the provisions of the DTPA.

55. The parties are adverse because Plaintiff and Defendant are in no way related to one another.

56. Plaintiff has a legally protectable interest in defending its products.

57. The issue is ripe for adjudication because the Defendant has demanded that Plaintiff cease selling Isodrene and The HCG Solution in Texas and has demanded that Plaintiff remove the products from store shelves in Texas. The Defendant has also warned that it may seek money damages should Plaintiff fail to comply with its demands.

58. Plaintiff is entitled to a declaratory judgment that its use of HCG in its product packaging and labeling has not violated any federal law, and that Plaintiff is entitled to use the letters HCG on its packaging and labeling for Isodrene and The HCG Solution.

**SECOND CLAIM FOR RELIEF—VIOLATION OF THE UNITED STATES  
CONSTITUTION**

**First Amendment--Prior Restraint Doctrine, Commercial Speech Doctrine,  
and Substantial Overbreadth Violations**

59. Plaintiff incorporates the above paragraphs herein.

60. As applied by the Defendants to the Plaintiff's commercial speech, the DTPA is an unconstitutional prior restraint in violation of the First Amendment. It also violates the First Amendment commercial speech doctrine. Moreover, the DTPA is substantially overbroad in violation of the First Amendment because it can be applied to violate the First Amendment rights of others not before the court.

61. Specifically, the Defendant has banned the use of truthful advertising related to lawful activities, which is protected by the First Amendment. Furthermore, the commercial speech banned by the Defendant is not inherently misleading.

**Fourteenth Amendment Due Process and Equal Protection**

62. Plaintiff incorporates the above paragraphs herein.

63. Plaintiff has a constitutionally protected liberty interest in the free expression of truthful commercial advertisements, unmolested by the Defendant. The Plaintiff has a right to

engage in lawful commerce through the marketing and sale of Plaintiff's lawful products (a core business activity of Plaintiff, developed through an extraordinary investment of time and money).

64. Plaintiff has a property interest in the intellectual property that forms the Plaintiff's products, in its investments in advertising and market research, and in the revenue derived from the manufacture and sale of Plaintiff's products.

65. The Fourteenth Amendment Due Process clause requires that the Defendant not deprive Plaintiff of its property interests without due process of law. The Defendant's actions to date have violated Plaintiff's right to due process of law.

66. Plaintiff accordingly seeks a declaration that Defendant's actions, including their asserted claim that Plaintiff's products violate federal law, constitute a present and ongoing violation of Plaintiff's Fourteenth Amendment Due Process rights.

67. Plaintiff has a constitutionally protected liberty interest in the free expression of commercial speech and in its right to engage in commerce through the marketing and sale of legal dietary supplements.

68. Defendant has violated Plaintiff's Fourteenth Amendment Due Process rights by depriving Plaintiff of its liberty and property interests without due process of law by directly causing retailers to remove the Products from store shelves without giving Plaintiff the opportunity to defend itself in a court of law or via an administrative process.

69. Defendant's actions constitute an ongoing and a continuous violation of Plaintiff's Fourteenth Amendment Due Process rights.

70. Similarly, Defendant's actions violate the equal protection afforded by the Fourteenth Amendment because Defendant seeks to prohibit Plaintiff from using the letters HCG

in the advertising of a dietary supplement. Such unilateral prohibition violates the equal protection clause of the Fourteenth Amendment because federal law allows for such use. Numerous companies utilize the name of a dietary ingredients, i.e. iron, potassium, calcium, water, etc. in the name of dietary supplements. By discriminating against Plaintiff for its use of “HCG” in the promotion of the Isodrene and The HCG Solution, while allowing other companies to use the name of prescription drugs in dietary supplement advertising, Defendant violates the Fourteenth Amendment guarantee of equal protection.

71. Plaintiff therefore seeks a declaration that Defendant's actions constitute a violation of Plaintiff's Fourteenth Amendment Equal Protection rights.

72. Plaintiff also is entitled to injunctive relief preventing Defendant from interfering with the sale and/or distribution of the Products pending resolution of this dispute.

#### **Violation of the Commerce Clause**

73. Plaintiff incorporates the above paragraphs herein.

74. Under Article 1, Section 8 of the United States Constitution, the United States Congress has the exclusive power and authority to regulate commerce among the several states.

75. The actions of the Defendant has substantially interfered with interstate commerce in that it has caused retailers to stop selling lawful products in States other than Texas.

76. Defendant's actions have damaged the Plaintiff.

77. Plaintiff therefore seeks a declaration that Defendant's actions constitute a violation of Plaintiff's rights under the United States Constitution.

78. Plaintiff is also entitled to injunctive relief preventing Defendant from interfering with the sale and/or distribution of the Products pending resolution of this dispute.

**THIRD CLAIM FOR RELIEF**  
**(Preliminary Injunction)**

79. Plaintiff incorporates the above paragraphs herein.

80. Defendant seeks to remove Plaintiff's products from retailers' shelves throughout Texas before obtaining any judicial determination that Plaintiff has in fact violated the DTPA.

81. If Defendant forces Plaintiff to remove the Products from the shelves in Texas and to cease all distribution and marketing of its products in Texas, Plaintiff will suffer immediate and irreparable harm.

82. Plaintiff is likely to prevail on the merits of its claims.

83. The benefit from a preliminary injunction outweighs any harm that might result from such an injunction.

84. A preliminary injunction would be for the public good.

85. Therefore, a preliminary injunction should be issued enjoining Defendant from interfering with the sale and/or distribution of Plaintiff's products pending resolution of this lawsuit.

**FOURTH CLAIM FOR RELIEF**  
**(Permanent Injunction)**

86. Plaintiff incorporates the above paragraphs herein.

87. Plaintiff is entitled to a permanent injunction prohibiting Defendant from interfering with the sale and marketing of its products in Texas while relying, as justification, on any of the matters related to those raised in the Letter.

WHEREFORE, Plaintiff prays for relief as follows:

A. For a Judgment declaring that Plaintiff is entitled to a declaratory judgment that its use of HCG in its product packaging and labeling has not violated any Federal law or Texas

law, and that Plaintiff is entitled to use the letters HCG on its packaging and labeling for Isodrene and The HCG Solution;

B. For a Preliminary Injunction enjoining Defendant from interfering with the sale and/or marketing of Plaintiff's products in Texas pending the resolution of this case;

C. For an Injunction prohibiting Defendant from interfering with the sale and marketing of Isodrene and The HCG Solution in Texas while relying, as justification, on an alleged violation as alleged in the October 26, 2011 letter;

D. For attorney fees and costs of Court as may be allowed by law; and

E. For any other relief deemed appropriate by this Court.

DATED this 3rd day of December, 2011.

Respectfully submitted,

WINSTEAD PC

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